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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,293	08/06/2001	Timothy W. Conner	16517.254	7785

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EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

94.

**Office Action Summary****Application No.**

09/922,293

**Applicant(s)**

CONNER ET AL.

**Examiner**

Lori A. Clow, Ph.D.

**Art Unit**

1631

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10 and 14-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicants' arguments, filed 9 June 2004, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 10 and 14-19 are currently pending.

### **Election/Restrictions**

Applicant argues again that the election of a single nucleic acid sequence is improper and that no serious burden would result by the search and examination of at least ten nucleotide sequences. Applicant argues that the Examiner has not provided a reason for this requirement. This is not persuasive and the Examiner would like to again point Applicant to the Office Action mailed 9 September 2003, in which the Examiner cited reference to MPEP 803.04, which states that "nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. The sequences are thus deemed to normally constitute independent and distinct inventions". In the requirement for Restriction, specific distinctions between multiple sequences were set forth and as such the requirement is still deemed proper. This requirement was made FINAL in the Office Action mailed 9 March 2004.

### **Claim Rejections - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10 and 14-19 remain rejected under 35 U.S.C. 101, for the reasons set forth in the previous Office Action, because the claimed invention lacks patentable utility.

Applicant's arguments with regard to the specification disclosing multiple uses for the claimed nucleic acids, including the identification of the presence or absence of a polymorphism, have been addressed previously (see Office Action of 9 March 2004, page 3, lines 11-19).

Applicant's arguments pertaining to the use of the present invention being analogous to the use of a microscope have been addressed previously (see Office Action of 9 March 2004, page 3, beginning line 20 to page 5, line 5).

Applicant's argument's with regard to the Examiner undermining existing utilities by stating that they are "nonspecific uses that are applicable to nucleic acids(s) or proteins in general" have been address in the Office Action dated 9 March 2004 (beginning page 5, line 19 to page 6, line 22).

Applicant argues that "the Examiner has not provided any evidence that would reasonably suggest that the claimed nucleic acids cannot be used for the Applicant's stated utilities". This is not persuasive. As clearly outlined in the Office Action dated 9 March 2004, none of the stated utilities for SEQ ID NO. 1 are specific utilities of SEQ ID NO. 1. Rather, the utilities are general to all disclosed sequences. A general discussion of purported utility does not meet the requirement for a specific utility under 35 USC 101. To reasonably confirm that a full or partial protein sequences were encoded by a particular SEQ ID and to determine how to use such proteins would require further experimentation. This is not a substantial utility. Identifying and studying the properties of a nucleic acid to determine if it encodes a protein and then identifying and studying the properties of the protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use.

With respect to credibility, Applicant is reminded that in order to meet the requirements of 35 USC 101, the specification must disclose at least one utility that is specific and substantial, as well as credible (absent a showing of well established utility, which would presume that the utility was credible). The claims have been rejected because 1) the specification fails to disclose at least one utility that is both specific and substantial, and 2) no convincing evidence has been presented to show that an EST, for which only its nucleotide sequence and source have been disclosed, has a well established utility.

Claims 10 and 14-19 remain rejected under 35 USC 112, first paragraph for the reasons set forth in the previous Office Action.

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1- and 14-19 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the previous Office Action, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have presented no new arguments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-19 recite “[...] a nucleic acids that shares between [...]”. It is unclear what limitation is intended by “share” in the instant claims. As share can mean to divide and distribute, to have in common, or to use partially, and it is unclear as to the intended meaning, the instant claims read on fragments of SEQ ID NO: 1 (see 102(b) rejection below).

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-19 are rejected under 35 U.S.C. 102(a) as being anticipated by AB035137 (August 9, 2000). AB035137 and SEQ ID NO:1 have an identity of 96.2%, thus meeting the limitation of “sharing” and identity somewhere within the sequence of SEQ ID NO:1.

Claims 15-19 are rejected under 35 U.S.C. 102(a) as being anticipated by AF296825 (August 23, 2000). AF296825 and SEQ ID NO:1 have an identity of 96.2%, thus meeting the limitation of “sharing” and identity somewhere within the sequence of SEQ ID NO:1.

Claims 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by D30807 (March 8, 1995). D30807 and SEQ ID NO:1 have an identity of 83.4%, thus meeting the limitation of “sharing” and identity somewhere within the sequence of SEQ ID NO:1.

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Claims 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by AF115821 (November 15, 1999). AB035137 and SEQ ID NO:1 have an identity of 78.4%, thus meeting the limitation of "sharing" and identity somewhere within the sequence of SEQ ID NO:1.

Claims 11 and 12 have been cancelled and therefore, the rejection under 35 USC 102 (b) has been withdrawn.

No claims are allowed.

### Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

August 23, 2004

Lori A. Clow, Ph.D.

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*Lori A. Clow*



MICHAEL P. WOODWARD  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

*8/24/04*